**21 USC 360bbb-3a: Emergency use of medical products**
Text contains those laws in effect on July 11, 2021

**From Title 21-FOOD AND DRUGS**
CHAPTER 9-FEDERAL FOOD, DRUG, AND COSMETIC ACT
SUBCHAPTER V-DRUGS AND DEVICES
Part E-General Provisions Relating to Drugs and Devices

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# §360bbb–3a. Emergency use of medical products

### (a) Definitions

In this section:

#### (1) Eligible product

The term "eligible product" means a product that-

(A) is approved or cleared under this subchapter, conditionally approved under section 360ccc of this title, or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262];

(B)(i) is intended for use to prevent, diagnose, or treat a disease or condition involving a biological, chemical, radiological, or nuclear agent or agents; or

(ii) is intended for use to prevent, diagnose, or treat a serious or life-threatening disease or condition caused by a product described in clause (i); and

(C) is intended for use during the circumstances under which-

(i) a determination described in subparagraph (A), (B), or (C) of section 360bbb–3(b)(1) of this title has been made by the Secretary of Homeland Security, the Secretary of Defense, or the Secretary, respectively; or

(ii) the identification of a material threat described in subparagraph (D) of section 360bbb–3(b)(1) of this title has been made pursuant to section 319F–2 of the Public Health Service Act [42 U.S.C. 247d–6b].

#### (2) Product

The term "product" means a drug, device, or biological product.

### (b) Expiration dating

#### (1) In general

The Secretary may extend the expiration date and authorize the introduction or delivery for introduction into interstate commerce of an eligible product after the expiration date provided by the manufacturer if-

(A) the expiration date extension is intended to support the United States ability to protect-

(i) the public health; or

(ii) military preparedness and effectiveness; and

(B) the expiration date extension is supported by an appropriate scientific evaluation that is conducted or accepted by the Secretary.

#### (2) Requirements and conditions

Any extension of an expiration date under paragraph (1) shall, as part of the extension, identify-

(A) each specific lot, batch, or other unit of the product for which extended expiration is authorized;

(B) the duration of the extension; and

(C) any other requirements or conditions as the Secretary may deem appropriate for the protection of the public health, which may include requirements for, or conditions on, product sampling, storage, packaging or repackaging, transport, labeling, notice to product recipients, recordkeeping, periodic testing or retesting, or product disposition.

#### (3) Effect

Notwithstanding any other provision of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.], an eligible product shall not be considered an unapproved product (as defined in section 360bbb–3(a)(2)(A) of this title) and shall not be deemed adulterated or misbranded under this chapter because, with respect to such

product, the Secretary has, under paragraph (1), extended the expiration date and authorized the introduction or delivery for introduction into interstate commerce of such product after the expiration date provided by the manufacturer.

**(4) Expiration date**

For purposes of this subsection, the term "expiration date" means the date established through appropriate stability testing required by the regulations issued by the Secretary to ensure that the product meets applicable standards of identity, strength, quality, and purity at the time of use.

**(c) Current good manufacturing practice**

**(1) In general**

The Secretary may, when the circumstances of a domestic, military, or public health emergency or material threat described in subsection (a)(1)(C) so warrant, authorize, with respect to an eligible product, deviations from current good manufacturing practice requirements otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this chapter, including requirements under section 351 or 360j(f)(1) of this title or applicable conditions prescribed with respect to the eligible product by an order under section 360j(f)(2) of this title.

**(2) Effect**

Notwithstanding any other provision of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.], an eligible product shall not be considered an unapproved product (as defined in section 360bbb–3(a)(2)(A) of this title) and shall not be deemed adulterated or misbranded under this chapter because, with respect to such product, the Secretary has authorized deviations from current good manufacturing practices under paragraph (1).

**(d) Emergency dispensing**

The requirements of subsections (b) and (f) of section 353, section 354, and section 360j(e) of this title shall not apply to an eligible product, and the product shall not be considered an unapproved product (as defined in section 360bbb–3(a)(2)(A) of this title) and shall not be deemed adulterated or misbranded under this chapter because it is dispensed without an individual prescription, if-

(1) the product is dispensed during the circumstances described in subsection (a)(1)(C); and

(2) such dispensing without an individual prescription occurs-

(A) as permitted under the law of the State in which the product is dispensed; or

(B) in accordance with an order issued by the Secretary, for the purposes and duration of the circumstances described in subsection (a)(1)(C).

**(e) Emergency use instructions**

**(1) In general**

The Secretary, acting through an appropriate official within the Department of Health and Human Services, may create and issue emergency use instructions to inform health care providers or individuals to whom an eligible product is to be administered concerning such product's approved, licensed, or cleared conditions of use.

**(2) Effect**

Notwithstanding any other provisions of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.], a product shall not be considered an unapproved product and shall not be deemed adulterated or misbranded under this chapter because of the issuance of emergency use instructions under paragraph (1) with respect to such product or the introduction or delivery for introduction of such product into interstate commerce accompanied by such instructions-

(A) during an emergency response to an actual emergency that is the basis for a determination described in subsection (a)(1)(C); or

(B) by a government entity (including a Federal, State, local, or tribal government entity), or a person acting on behalf of such a government entity, in preparation for an emergency response.

(June 25, 1938, ch. 675, §564A, as added Pub. L. 113–5, title III, §302(b), Mar. 13, 2013, 127 Stat. 183 ; amended Pub. L. 114–255, div. A, title III, §3088(c), Dec. 13, 2016, 130 Stat. 1149 ; Pub. L. 116–22, title VII, §705(c), June 24, 2019, 133 Stat. 964 .)

## Editorial Notes

### References in Text

The Public Health Service Act, referred to in subsecs. (b)(3), (c)(2), and (e)(2), is act July 1, 1944, ch. 373, 58 Stat. 682 , which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public

Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

## AMENDMENTS

**2019**-Subsec. (e)(2)(A). Pub. L. 116–22 substituted "subsection (a)(1)(C)" for "subsection (a)(1)(C)(i)".

**2016**-Subsec. (a)(1)(A). Pub. L. 114–255, §3088(c)(1), inserted ", conditionally approved under section 360ccc of this title," after "subchapter".

Subsec. (d). Pub. L. 114–255, §3088(c)(2), substituted "subsections (b) and (f) of section 353, section 354, and section 360j(e) of this title" for "sections 353(b) and 360j(e) of this title" in introductory provisions.